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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/017,800 | 12/12/2001 | Eric G. Lovett | 279.353US1 | 9663 |

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

| EXAMINER | |
|---|---|
| EVANISKO, GEORGE ROBERT | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | |

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/017,800 | LOVETT ET AL. | |
| | Examiner | Art Unit | |
| | George R. Evanisko | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *7-14,21-27 and 33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,15-20 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/06 has been entered.

### *Election/Restrictions*

Claims 7-14, 21-27, and 33-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions/embodiments, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/10/04.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 15-20, 29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Contak TR CHFD" System Guide in view of Stroebel et al (5725561).

The System Guide describes the use of rate smoothing (pages 6-28 - 6-30) that can be used for atrial modes and atrial rates (page 6-28), using/selecting different upward and downward percentages (page 6-30) when the rate smoothing is programmed on, the use of atrial and ventricular leads with a rate adaptive sensor (page i), and sensing the heart signals in the different modes. It is inherent that the system have a signal input circuit and control circuit since the pacemaker receives heart signals and adjusts the rate smoothing based on the received signals. But the System Guide does not describe the use of a sense amplifier and the controller using a state detector to detect a predetermined state, such as a heart rate state, to select/activate/use the rate smoothing percentages based on whether the state is present. Stroebel discloses the claimed invention using a cardiac electrode, 14, and sense amplifier, 24, with CPU, 32, and time interval between heart beats to activate/select the smoothing algorithm (column 9) to condition and amplify the signal so it can be processed by the CPU/controller. In addition, Stroebel teaches that it is known to use a state detector to detect a predetermined heart rate state or cardiac rhythm state (the time interval between two beats) to activate/select/use the rate smoothing based on whether the state is present to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate (columns 9 and 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rate smoothing pacer and method as taught by the System Guide, with an amplifier

and a state detector to detect a predetermined heart rate state to activate/select or adjust the rate smoothing based on whether the state is present as taught by Stroebel, since such a modification would provide a rate smoothing pacer that uses an amplify to condition and amplify the cardiac signals so they can be used by the CPU/controller and to use a signal state detector to detect a predetermined heart rate state to activate/select/use the rate smoothing based on whether the state is present, and therefore would activate/select the up and down percentages when activated, to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate.

In addition, Stroebel teaches using the time interval between heart beats, which is a "heart rate state" or a "cardiac rhythm state". In the alternative, Stroebel discloses the claimed invention except for determining the heart rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time interval between beats as taught by Stroebel, with the use of heart rate since it was known in the art that the time interval between beats and heart rate are functional equivalents ( 60 x 1/heart rate = time interval between beats) that can be used interchangeably depending on the design choice of the system and calculations being used and because the two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the time interval between beats for the heart rate.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as obvious over the System Guide in view of Stroebel. The state detector of the System Guide in view of Stroebel will include some sort of comparator with a threshold input to compare the two and will include an output when the

predetermined state occurs since the device operates when certain thresholds are reached (claim 3).

In the alternative, the System Guide in view of Stroebel discloses the claimed invention except for the comparator with threshold input and state output. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacemaker system and method as taught by the System Guide in view of Stroebel, with a comparator with threshold input and state output since it was known in the art that pacemaker systems and methods use a comparator with threshold input and state output to compare the heart rate to different predetermined inputs to provide an output of the comparison to allow the pacemaker to easily determine if a particular event has occurred.

Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the System Guide in view of Stroebel.

The System Guide in view of Stroebel discloses the claimed invention except for using a look-up table to map and select the first and second rate smoothing percentages to the predetermined state (claims 28 and 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacemaker system and method as taught by the System Guide in view of Stroebel, with a look-up table to map and select the first and second rate smoothing percentages to the predetermined state since it was known in the art that pacemaker systems and methods use look-up tables to map and select different values to predetermined states to save computational time and energy and to provide different values to better meet the needs of the patient.

### *Response to Arguments*

Applicant's arguments filed 1/18/06 have been fully considered but they are not persuasive. The argument that the System Guide or Stroebel do not teach "that the rate smoothing percentages are selected based on whether the predetermined state is present" is not persuasive. The System Guide "selects"/activates/uses the previously programmed percentage to control the largest increase or decrease allowed in the pacing rate when the intrinsic or sensor rate is increasing/decreasing (see page 6-29 of the System Guide). Although the percentage is set, the pacer still "selects" the previously set percentage value to use as the value to control the pacing rate. In addition, Stroebel does not specifically state that rate increase smoothing should not be used or should be avoided, but that the sudden rate increase does not "appear" to require smoothing. Therefore Stroebel does not teach against rate increase smoothing and leaves the door open to that possibility. Also, Stroebel is only used to show that it is known to use a sensor to indicate when smoothing should take place to select/use the rate smoothing and not to provide a limit in a pacing rate increase or decrease.

### *Conclusion*

This is a RCE of applicant's earlier Application No. 10/017800. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
February 21, 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/21/6